

REMARKS

Applicants note that all amendments, cancellations, and additions of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the Office Action mailed 4/2/08, the Examiner objected to the lack of status identifiers in the priority claim. The Applicants have amended the claims to include reference to the status of the prior filed patent applications. As such, the applicants submit that the priority claim is proper.

In the Office Action mailed 4/2/08, the Examiner objected to the declaration due to an error in the serial number of application 09/398,552. The Applicants have obtained a substitute declaration from the inventors and attach said declaration hereto.

In the Office Action mailed 4/2/08, the Examiner objects to the specification as allegedly containing trademarks. In particular, the Examiner objects to the use of the alleged trademarks "cocaine" and "polyurethane." The Applicants respectfully disagree and submit that cocaine and polyurethane are not used as tradenames or trademarks in the present specification. A search of the PTO electronic trademark database (TESS) revealed no matches for polyurethane and only trademarks related to cosmetics and other non-scientific uses of cocaine. The Applicants submit that both "cocaine" and "polyurethane," as used in the present specification, are used as nouns to describe chemical compounds, not as trademarks. As such, the objection should be withdrawn.

In the Office Action mailed 4/2/08, the Examiner issued several rejections. Each of the rejections is discussed in detail below.

I. The Claims are Definite

The Examiner rejects Claim 1 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite because "it is not clear what the term "potassium iodide chromagen" will encompass." (Office Action, pg. 6). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments

¹ 65 Fed. Reg. 54603 (Sept., 8, 2000).

or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have amended Claim 1 to recite that the reaction site comprises a chromagen, wherein said chromagen is potassium iodide. As such, the Applicants submit that the claims are definite and respectfully request that the rejection be withdrawn.

The Examiner further rejects Claim 9 under 35 U.S.C. 112, second paragraph as allegedly being indefinite because "it is not clear as to how many chromagens will be found on the reaction site." (Office action, pg. 6). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have canceled claim 9. As such, the rejection is moot.

II. The Claims are Supported by Written Description

The Examiner rejects Claims 1, 2-15, 20-24 and 74 under 35 U.S.C. 112, first paragraph as allegedly lacking written description. The Examiner states "Claim 1 recites "potassium iodide chromagen" however support for this has not been found in the instant specification." (Office Action, pg. 7). The Applicants respectfully disagree. As described above, the claims have been amended to recite that the reaction site comprises a chromagen, wherein said chromagen is potassium iodide. As the Examiner has indicated that the specification supports such language (Office Action, pg. 7), the Applicants respectfully request that the rejection be withdrawn.

The Examiner further rejects Claim 74 under 35 U.S.C. 112, first paragraph, as allegedly lacking written description. The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have amended Claim 1 to include the elements of Claim 74 (See below) and canceled Claim 74. Amended Claim 1 recites that a color change occurs at a sample concentration equivalent to a blood

alcohol concentration at or above 0.04% and wherein no color change occurs at blood alcohol concentrations significantly under 0.04%. As requested by the Examiner (Office Action, pg. 8), the amended Claim 1 directly tracks the language of the specification at page 45, lines 5-27. As such, the Applicants submit that the claims are supported by adequate written description and respectfully request that the rejection be withdrawn.

III. The Claims are Novel

The Examiner rejects Claims 1-4 and 11 as allegedly anticipated under 35 U.S.C. § 102(b) by Sangha (US 5,334,502; hereinafter Sangha) as evidence by Levitskii et al (Ukrainskii Biokimicheskii Zhurnal, 1979, 51:3, p. 289; English abstract only; hereinafter Levitski). The Applicants respectfully disagree and submit that Sangha does not teach every element of the claims as required for rejection under 35 U.S.C. 102. In particular, Sangha does not teach the claim element of exposing the assay test reaction site to the inside of a subject's mouth. See, e.g., Sangha, Column 5, Lines 44-54, Column 8, Lines 3-17, Column 8, Lines 37-52, Column 8, Lines 53-64. In each embodiment described by Sangha, the assay test reaction site is segregated from the inside of a subject's mouth. As such, Sangha does not teach every element of the claims as required for rejection under 35 U.S.C. 102. The Applicants note that Sangha was cited against the present application in the Office Action mailed December 4, 2002 and the Applicants successfully traversed the rejection on the grounds described above. Thus, the re-application of Sangha as prior art is improper.

The Applicants further submit that Sangha does not teach the claim element of a potassium iodide chromagen. The Examiner states "However, this is deemed inherent to the teachings of Sangha because potassium iodide is a known substrate for peroxidase activity in saliva." The Applicants respectfully disagree and submit that the Examiner has improperly applied rejection by inherency. As stated in M.P.E.P. 2112:

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) and

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

The Examiner has provided no intrinsic or extrinsic evidence that potassium iodide **is present** in the teachings of Sangha, inherently or otherwise. The fact that it could possibly be present or useful (which the Applicants submit it is not) does not constitute an inherent property or characteristic. As such, rejection by inherency is not applicable to the presently claimed invention.

The Applicants assert that the Examiner's rejections are in error. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have amended Claim 1 to recite that the analyte is ethanol, and that the reaction results in a visibly detectable color change at or above a saliva concentration of ethanol corresponding to a blood alcohol concentration of 0.4% and canceled Claims 20-24 and 74. Sangha does not teach or suggest the claim elements of exposing the assay reaction site to the inside of a subject's mouth, the analyte being ethanol, the chromagen being potassium iodide, or a visibly detectable signal above a threshold level of blood alcohol. As such, Sangha does not teach all of the elements of the claims as required for rejection under 35 U.S.C. 102. Accordingly, the rejection should be withdrawn.

IV. The Claims are Non-Obvious

The Examiner rejects Claim 7 under 35 U.S.C. 103 as allegedly being obvious in light of Sangha as evidenced by Levitski in view of Spring. The Applicants respectfully disagree and submit that the Examiner has not demonstrated a prima facie case of obviousness because the cited references do not teach all of the elements of the claims. Neither Sangha nor Spring, alone or in combination teach the claim elements of exposing the assay test reaction site to the inside of a subject's mouth, the analyte being ethanol, the chromagen being potassium iodide, or a visibly detectable signal above a threshold level of blood alcohol. As such, the cited references

do not teach all of the elements of the claims as required for rejection under 35 U.S.C. 103 and the rejection should be withdrawn.

The Examiner further rejects Claims 6 and 12-15 under 35 U.S.C. 103 as allegedly being obvious in light of Sangha as evidenced by Levitski in view of Bogema (US 6,248,598; hereinafter Bogema). The Applicants respectfully disagree and submit that the Examiner has not demonstrated a prima facie case of obviousness because the cited references do not teach all of the elements of the claims. Neither Sangha nor Bogema, alone or in combination teach the claim elements of exposing the assay test reaction site to the inside of a subject's mouth, the analyte being ethanol, the chromagen being potassium iodide, or a visibly detectable signal above a threshold level of blood alcohol. As such, the cited references do not teach all of the elements of the claims as required for rejection under 35 U.S.C. 103 and the rejection should be withdrawn.

The Examiner further rejects Claims 5, 8-10, 20-22 and 74 under 35 U.S.C. 103 as allegedly being obvious in light of Sangha as evidenced by Levitski in view of Titmas (US 5,334,502; hereinafter Titmas). The Applicants respectfully disagree and submit that the Examiner has not demonstrated a prima facie case of obviousness because the cited references do not teach all of the elements of the claims. Neither Sangha nor Titma, alone or in combination teach the claim element of the chromagen being potassium iodide. As described above, Sangha does not teach a potassium iodide chromagen, nor does Titma. As such, the cited references do not teach all of the elements of the claims as required for rejection under 35 U.S.C. 103 and the rejection should be withdrawn.

The Examiner further rejects Claims 23-24 under 35 U.S.C. 103 as allegedly being obvious in light of Sangha as evidenced by Levitski in view of Tabb (US 4,440,724; hereinafter Tabb). Claims 23-24 have been canceled. As such, the rejection is moot.

Nothing in any of the cited references teaches or suggests that potassium iodide is capable of acting as a successful chromagen that: 1) is compatible with in mouth saliva; and 2) produces a visible color change in response to particular alcohol concentrations (but not others) correlated with blood alcohol levels; i.e. the art does not teach or suggest that potassium iodide is a sufficiently sensitive and robust chromagen to function as claimed.

CONCLUSION

All grounds of rejection of the Office Action mailed 4/02/03 have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicants' claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: July 2, 2008

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